

CLAIMS:

The invention is claimed as follows:

1. A system for providing peritoneal dialysis to a patient, the system
5 comprising:

a catheter having an inflow lumen and an outflow lumen in
communication with the patient's peritoneal cavity;

a fluid circuit in fluid communication with the catheter thereby defining
a closed fluid path capable of circulating fluid into, through and out of the peritoneal
10 cavity;

a supply of dialysate coupled to the fluid circuit;

a cyclor that pumps the dialysate into the fluid circuit and circulates the
dialysate during a treatment period along the closed fluid path to remove a
therapeutically effective amount of solutes and ultrafiltrate from the patient;

15 a cleaning device coupled to the fluid circuit wherein the cleaning
device is capable of removing an amount of the solutes from the dialysate including at
least a portion of urea; and

a discharge path coupled to the fluid circuit allowing the fluid circuit to
be drained of fluid after the treatment period.

20

2. The system of Claim 1 wherein the treatment period comprises about
eight hours or less.

3. The system of Claim 1 wherein the system employs about 6 liters or
25 less of dialysate to treat the patient.

4. The system of Claim 1 wherein the cleaning device includes non-
selectively removing solutes from the dialysate.

30 5. The system of Claim 4 wherein the cleaning device includes a sorbent
material selected from the group consisting of carbon, activated charcoal, and
combinations thereof.

6. The system of Claim 5 wherein the cleaning device does not include a material capable of selectively removing urea.

5 7. The system of Claim 1 wherein the dialysate is circulated along the closed fluid path in a continuous manner.

8. The system of Claim 7 wherein the supply of dialysate includes a first supply and a second supply that can be separately fed into and circulated along the
10 closed fluid path of the fluid circuit during consecutive treatment periods of about 4 hours or less.

9. A system for providing peritoneal dialysis to a patient, the system comprising:

15 a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity;

a fluid circuit in fluid communication with the catheter thereby defining a closed fluid path capable of circulating a therapy fluid into, through and out of the peritoneal cavity;

20 a first supply of the therapy fluid including a dialysate coupled to the fluid circuit;

a cyclor that pumps the dialysate into the fluid circuit and circulates the dialysate along the closed fluid path during a treatment period to remove a therapeutically effective amount of solutes and ultrafiltrate from the patient;

25 a second supply of the therapy fluid including an osmotic agent solution coupled to the fluid circuit wherein the cyclor can pump the second supply of fluid into the fluid circuit during the treatment period;

a cleaning device coupled to the fluid circuit wherein the cleaning device is capable of removing solutes including at least a portion of urea from the
30 therapy fluid as it circulates along the closed fluid path;

a reservoir coupled to the fluid circuit wherein the reservoir is adapted to provide a variable increase in volume capacity to the fluid circuit allowing the

system to compensate for an increase in fluid volume in the fluid circuit during treatment; and

a discharge path coupled to the fluid circuit allowing the fluid circuit to be drained of fluid after the treatment period.

5

10. The system of Claim 9 wherein the treatment period comprises about eight hours or less.

11. The system of Claim 9 wherein the first supply contains about 6 liters
10 or less of dialysate.

12. The system of Claim 9 wherein the second supply contains about 3 liters or less of the osmotic agent solution.

13. The system of Claim 12 wherein the osmotic agent solution is selected
15 from the group consisting of a 2.5% dextrose-based solution, a 3.5% dextrose-based solution, a 4.25% dextrose-based solution, a greater than 4.25% dextrose-based solution and combinations thereof.

14. The system of Claim 9 wherein the osmotic agent solution contains
20 about 4.25% or more of dextrose and one or more electrolytes at a concentration higher than existing levels in the fluid circulating through the fluid circuit.

15. The system of Claim 14 wherein the second supply contains about 1
25 liter or less of the osmotic agent solution.

16. The system of Claim 9 wherein the cleaning device is capable of non-selectively removing solutes from the therapy fluid.

17. The system of Claim 16 wherein the cleaning device includes a sorbent
30 material selected from the group consisting of carbon, activated charcoal, and combinations thereof in addition to a material capable of selectively removing at least a portion of the urea from the dialysate.

18. A system for providing peritoneal dialysis to a patient, the system comprising:

5 a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity;

a fluid circuit in fluid communication with the catheter thereby defining a closed fluid path capable of circulating a therapy fluid into, through and out of the peritoneal cavity;

10 a first supply of the therapy fluid including a dialysate coupled to the fluid circuit;

a cyclor that pumps the dialysate into the fluid circuit and circulates the dialysate along the closed fluid path during a treatment period to remove a therapeutically effective amount of solutes and ultrafiltrate from the patient;

15 a second supply of the therapy fluid including an osmotic agent solution coupled to the fluid circuit wherein the cyclor pumps the second supply into the fluid circuit during the treatment period;

20 a cleaning device coupled to the fluid circuit wherein the cleaning device is capable of removing solutes from the therapy fluid including a therapeutically effective portion of urea from the therapy fluid as the therapy fluid circulates along the closed fluid path; and

a discharge path coupled to the fluid circuit allowing the fluid circuit to be drained of the therapy fluid at an effective rate to compensate for an increase in therapy fluid volume in the fluid circuit due to the second supply of fluid and the ultrafiltrate.

25 19. The system of Claim 18 wherein the treatment period comprises about eight hours or less.

20. The system of Claim 18 wherein the first supply contains about 6 liters or less of dialysate.

30

21. The system of Claim 18 wherein the second supply contains about 3 liters or less of the osmotic agent solution.

22. The system of Claim 21 wherein the osmotic agent solution is selected from the group consisting of a 2.5% dextrose-based solution, a 3.5% dextrose-based solution, a 4.25% dextrose-based solution, a greater than 4.25% dextrose-based solution and combinations thereof.

23. The system of Claim 18 wherein the osmotic agent solution contains about 4.25% or more of dextrose and a concentration of one or more electrolytes higher than a level of electrolytes in the therapy fluid.

24. The system of Claim 23 wherein the second supply contains about 1 liter or less of the osmotic agent solution.

25. The system of Claim 18 wherein the cleaning device is capable of non-selectively removing solutes from the therapy fluid.

26. The system of Claim 25 wherein the cleaning device includes a sorbent material selected from the group consisting of carbon, activated charcoal, and combinations thereof in addition to a material capable of selectively removing at least a portion of the urea from the dialysate.

27. The system of Claim 26 wherein the cleaning device further includes a material capable of selectively removing at least a portion of phosphates from the therapy fluid.

28. A system for providing peritoneal dialysis to a patient, the system comprising:

a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity;

a fluid circuit in fluid communication with the catheter thereby defining a closed fluid path capable of circulating fluid into, through and out of the peritoneal cavity;

a supply of dialysate coupled to the fluid circuit;
a cyclor that pumps the dialysate into the fluid circuit and circulates the dialysate during a treatment period along the closed fluid path to remove a therapeutically effective amount of solutes and ultrafiltrate from the patient;
5 a cleaning device coupled to the fluid circuit wherein the cleaning device is capable of removing an amount of the solutes from the dialysate including at least a portion of urea; and
a discharge path coupled to the fluid circuit allowing the fluid circuit to be drained of fluid wherein the system is capable of obtaining a clearance level
10 including about 2.1 to about 2.6 for urea.

29. The system of Claim 28 wherein the clearance level further includes about 72 l/wk to about 90 l/wk for creatinine.

15 30. The system of Claim 28 wherein the clearance level further includes about 3.5 g/wk for phosphate.

31. The system of Claim 28 wherein the clearance level further includes about 600 mg/wk for β_2 microglobulin.

20 32. A method of providing peritoneal dialysis to a patient, the method comprising the steps of:

coupling a fluid circuit in fluid communication with a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

25 supplying a source of the fluid including a dialysate to the fluid circuit;
circulating the dialysate along the closed fluid path;
increasing a volume capacity of the fluid circuit to compensate for an increase in fluid volume in the fluid circuit;
removing an amount of solutes from the fluid as the fluid circulates
30 along the closed fluid path; and
draining the fluid circuit of fluid after treatment.

R 126

³³
29. The method of Claim 28 further comprising treating the patient for a period of about eight hours or less.

³⁴
30. The method of Claim 28 wherein about 6 liters or less of dialysate is
5 supplied during treatment.

³⁵
31. The method of Claim 28 wherein about 1.5 liters or less of ultrafiltrate is added to the fluid circuit during treatment.

³⁶
32. The method of Claim 28 wherein a sorbent material including carbon is
10 employed to non-selectively remove the solutes from the dialysate.

³⁷
33. The method of Claim 32 wherein at least a portion of urea is selectively removed from the dialysate.

15 ³⁸
34. A method of providing peritoneal dialysis to a patient, the method comprising the steps of:

coupling a fluid circuit in fluid communication to a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a
20 therapy fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

supplying a first source of a therapy fluid including a dialysate to the fluid circuit;

25 supplying a second source of the therapy fluid including an osmotic agent solution to the fluid circuit;

circulating the therapy fluid along the closed fluid path;

increasing a volume capacity of the fluid circuit to compensate for an increase in fluid volume due to the ultrafiltrate and the osmotic agent solution;

30 removing an amount of solutes including a therapeutically effective portion of urea from the therapy fluid as the therapy fluid circulates; and draining the fluid circuit of fluid after treatment.

R126
35. The method of Claim 34 further comprising treating the patient for a period of about eight hours or less.

36. The method of Claim 34 wherein about 6 liters or less of the dialysate is added to the fluid circuit during treatment.

37. The method of Claim 34 wherein about 1.5 liters or less of ultrafiltrate is added to the fluid circuit during treatment.

38. The method of Claim 34 wherein about 3 liters or less of the osmotic agent solution is added to the fluid circuit during treatment in which the osmotic agent solution is selected from the group consisting of a 2.5% dextrose-based solution, a 3.5% dextrose-based solution, a 4.25% dextrose-based solution, a greater than 4.25% dextrose-based solution and combinations thereof.

39. The method of Claim 38 wherein about 1 liter or less of the osmotic agent solution is added to the fluid circuit during treatment in which the osmotic agent solution contains about 4.25% or more of dextrose.

40. The method of Claim 34 wherein a sorbent material including carbon is employed to non-selectively remove solutes from the therapy fluid in addition to a material capable of selectively removing at least a portion of urea from the therapy fluid.

41. A method of providing peritoneal dialysis to a patient, the method comprising the steps of:

coupling a fluid circuit in fluid communication to a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a therapy fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

supplying a first source of therapy fluid including a dialysate to the fluid circuit;

supplying a second source of the therapy fluid including an osmotic agent solution to the fluid circuit;

circulating the dialysate and the osmotic agent solution along the closed fluid path;

5 removing a therapeutically effective amount of solutes and ultrafiltrate from the therapy fluid including a therapeutically effective portion of urea; and

draining the fluid circuit of fluid at an effective rate to compensate for an increase in fluid volume due to the second supply of the therapy fluid and the ultrafiltrate.

10

R126
~~46~~
42.

The method of Claim 41 further comprising treating the patient in about eight hours or less.

~~47~~
43.

15 The method of Claim 41 wherein about 6 liters or less of the dialysate is added to the fluid circuit during treatment.

~~48~~
44.

The method of Claim 41 wherein about 1.5 liters or less of ultrafiltrate is added to the fluid circuit during treatment.

20

~~49~~
45.

The method of Claim 41 wherein about 6 liters or less of the osmotic agent solution is added to the fluid circuit during treatment.

~~50~~
46.

25 The method of Claim 45 wherein the osmotic agent solution is selected from the group consisting of a 2.5% dextrose-based solution, a 3.5% dextrose-based solution, a 4.25% dextrose-based solution, a greater than 4.25% dextrose-based solution and combinations thereof.

~~51~~
47.

30 The method of Claim 41 wherein the osmotic agent solution contains about 4.25% or more of dextrose and a concentration of one or more electrolytes elevated above a level of electrolytes in the therapy fluid.

48. The method of Claim 47 wherein about 1 liter or less of the osmotic agent solution is added to the fluid circuit during treatment.

49. The method of Claim 41 wherein a sorbent material including carbon is employed to non-selectively remove solutes in addition to a material which is capable of selectively removing at least a portion of the urea from the therapy fluid as the therapy fluid circulates along the closed fluid path.

50. The system of Claim 49 wherein a material is employed to selectively remove at least a portion of phosphates from the therapy fluid.

51. A method of reducing an amount of dialysate used during dialysis therapy, the method comprising the steps of:

coupling a fluid circuit in fluid communication to a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

supplying a source of the fluid including a dialysate in an amount of about 6 liters or less to the fluid circuit;

circulating the dialysate along the closed fluid path;

increasing a volume capacity of the fluid circuit to compensate for an increase in fluid volume in the fluid circuit due to removal of the ultrafiltrate from the patient; and

removing an amount of solutes from the therapy fluid as the therapy fluid is continuously circulated.

52. The method of Claim 51 wherein about 1.5 liters or less of ultrafiltrate is added to the fluid circuit during treatment.

53. The method of Claim 51 wherein a sorbent material selected from the group consisting of carbon, activated charcoal and combinations thereof is used to non-selectively remove the solutes from the dialysate.

R126
54. The method of Claim 53 wherein at least a portion of urea is selectively removed from the therapy fluid without use of an enzyme including urease.

55. The method of Claim 51 wherein a solution capable of enhancing diffusive properties of the dialysate is added to the fluid circuit during treatment.

56. The method of Claim 54 wherein the solution comprises an osmotic agent solution selected from the group consisting of a 2.5% dextrose-based solution, a 3.5% dextrose-based solution, a 4.25% dextrose-based solution, a greater than 4.25% dextrose-based solution and combinations thereof.

57. A method of providing peritoneal dialysis to a patient, the method comprising the steps of:
coupling a fluid circuit in fluid communication with a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;
supplying a source of the therapy fluid including a dialysate to the fluid circuit;
circulating the dialysate along the closed fluid path;
removing an amount of solutes from the therapy fluid as the therapy fluid is circulated;
draining the fluid circuit of fluid after treatment; and
obtaining a clearance level including about 2.1 to about 2.6 for urea.

58. The method of Claim 57 wherein the clearance level of about 72 l/wk to about 90 l/wk for creatinine is further obtained.

59. The method of Claim 57 wherein the clearance level of about 3.5 g/wk for phosphate is further obtained.

60. The method of Claim 57 wherein the clearance level of about 600 mg/wk for β_2 microglobulin is further obtained.

Re 26

65
61.

The method of Claim 57 wherein at least a portion of urea is selectively removed from the therapy fluid without an enzyme including urease.